



Virginia
Regulatory
Town Hall

Periodic Review and
Notice of Intended Regulatory Action
Agency Background Document

Agency Name:	Board of Corrections
VAC Chapter Number:	6 VAC 15-26-10 et seq.
Regulation Title:	Regulations for Human Subject Research
Action Title:	NOIRA
Date:	April 13, 2001

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

Regulations for Human Subject Research establish conditions, standards and procedures that facilitate the agency's review and approval of human research, on an informed consent basis, of offenders and employees. In accordance with legislation, the regulations define requirements for obtaining informed consent and require the establishment of human research review committees that review and approve all human research activities. These regulations apply to the Department of Corrections and to any facility, program or organization owned, operated, funded, or licensed by the department, which conducts, proposes to conduct, or authorizes research using human participants.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

Under the authority of Section 53.1-5.1 of the Code of Virginia, the Board of Corrections promulgates these regulations pursuant to the Administrative Process Act (Section 9-6.14:1 et seq.) to effectuate the provisions of Chapter 5.1 (Section 32.1-162.16 et seq.) of Title 32.1 for human research.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

An announcement of the board's periodic review of the Regulations for Human Subject Research was posted on the Virginia Regulatory Townhall website, and was sent to the Registrar of Regulations for initial publication on 2/26/01. Public comment was solicited through the end of business on 3/30/01. During the public comment period, no comments were received from members of the public.

The board will hold another 30-day public comment period on the Notice of Intended Regulatory Action and a 60-day public comment period on the proposed regulation. Any comments received during public comment periods shall be given due consideration in the amendment of this regulation.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

Broad goals for this regulation are to further define and clarify requirements for obtaining informed consent and the establishment of human research review committees. Individuals affected by these regulations include all parties interested in submitting proposals for human subject research to the department, all inmates, probationers, parolees, and employees of the department who consent to participate in research, and each organizational unit of the department that conducts or proposes to conduct, or authorizes research using human participants. These regulations should not affect one entity more so than another, nor should

they impose any monetary demand upon any entity. It is not expected that the board or department will receive opposition to these regulations.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The Board of Corrections could consider no other alternative than to promulgate regulations for human subject research. Section 53.1-5.1 of the Code of Virginia specifically requires that the board establish regulations that effectuate the provisions of Chapter 5.1 section 32.1-162.16 et seq. of Title 32.1 for human research.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The board is recommending amendments to its Regulations for Human Subject Research to increase efficiency in the Committee review process. Updating regulations should enable the agency to ensure compliance with these legislatively mandated regulations.

Substance

Please detail any changes that would be implemented.

An area that has been identified as needing clarification or inclusion into the Regulations for Human Subject Research, including: committee review for research being conducted by another state agency in conjunction with the Department of Corrections

Family Impact Statement

Please provide a preliminary analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

It is not anticipated that the regulatory action being considered will have an impact on the institution of family or family stability; however the board will take under consideration any public comment in this area.